



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR          | ATTORNEY DOCKET NO.               | CONFIRMATION NO. |
|---|-------------|-------------------------------|-----------------------------------|------------------|
| 09/743,787  | 01/06/2004  | Alberto Guillermo Suzarte Paz | 024273-00001                      | 8586             |
| 4372  | 7590        | 10/22/2008                    |                                   |                  |
| ARENT FOX LLP<br>1050 CONNECTICUT AVENUE, N.W.<br>SUITE 400<br>WASHINGTON, DC 20036 |             |                               | EXAMINER<br>ROGERS, JAMES WILLIAM |                  |
|   |             |                               | ART UNIT                          | PAPER NUMBER     |
|   |             |                               | 1618                              |                  |
|   |             |                               | NOTIFICATION DATE                 | DELIVERY MODE    |
|   |             |                               | 10/22/2008                        | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com

IPMatters@arentfox.com

Patent\_Mail@arentfox.com

# **Advisory Action** **Before the Filing of an Appeal Brief**

|                                      |   |
|--------------------------------------|---|
| <b>Application No.</b><br>09/743,787 | <b>Applicant(s)</b><br>SUZARTE PAZ ET AL. |
| <b>Examiner</b><br>JAMES W. ROGERS   | <b>Art Unit</b><br>1618                   |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 08 September 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## **NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

## **AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

## **AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

## **REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Continuation of 11, does NOT place the application in condition for allowance because: While applicants assert it is incorrect to state that the water content and residual monomer content would be less than 1.5% in a polymer melt, they provide no more than conclusory statements to assert that Yang does not disclose such low amounts. As noted before since PVAc was commercially purchased and added as an ingredient to an encapsulation material it would be obvious that by controlling the melt temperature PVAc could essentially be free of water, since it was commercially available and was further processed by melt with the other ingredients of the composition. Thus by the melt processing it would be obvious that essentially any amount of residual monomer VAc present within the commercially bought PVAc would have boiled off during processing. Furthermore as noted in the previous office action since PVAc was commercially bought it would be obvious to one of ordinary skill in the art to select a commercially available PVAc which would have low impurity content since the polymer is used in an oral pharmaceutical formulation. It is also considered to be ordinary and routine experimentation by the examiner for one of ordinary skill in the art to purify a polymer to a high degree if it is to be used in an orally administrable dosage form. It is further noted by the examiner that applicants arguments are conclusory in nature about the amounts of water and impurities and applicants have not showed any experimental results in which the PVAc after processing into the pharmaceutical formulations of Yang would not have the claimed residual impurities and water content. In regards to applicants statement that one of ordinary skill would know that water could not be used to solvate PVAc, while applicants very well may be correct in this assumption it is noted that the claims do not exclude the fact that PVAc does not have to be dissolved in the solution, for instance it could read on a dispersion or emulsion. Applicants further assert in a conclusory manner that the examiner improperly assumed that PVAc has a low water content because it was dried in a desiccator in Sa. Applicants once again rely on the argument that the method described in Sa is not an industrial one. The relevance of these assertions is unclear. Sa does not use water in the method to produce the microspheres and any water present within the commercially bought PVAc would have been removed during filtration with n-hexane and/or during the drying process in the vacuum desiccator. Regarding applicants assertion that their process is an industrial process and is not restricted to production of microspheres, as currently amended applicants claims do not preclude the use of non-industrial processes to produce the pharmaceutical formulation nor have applicants provided evidence besides conclusory statements as to why Sa does not teach a process that could be scaled up to an industrial process. As previously stated applicants arguments are conclusory in nature on the amounts of water and impurities and applicants have not showed any experimental results in which the PVAc after processing into the pharmaceutical formulations of Sa would not have the claimed residual impurities and water content. The solution to this problem is simple, submit experimental evidence that the methods used in Sa and Yang would not produce PVAc with the residual amounts of water and VAc.